

MEDICINE BOARD[653]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)“b.”

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 147.76, the Board of Medicine hereby proposes to amend Chapter 13, “Standards of Practice and Principles of Medical Ethics,” Iowa Administrative Code.

The purpose of Chapter 13 is to establish standards of medical practice for medical physicians and osteopathic physicians. The proposed rule establishes the standards of practice for physicians who use telemedicine, which is the practice of medicine using electronic communication, information technology or other means of interaction between a licensee in one location and a patient in another location with or without an intervening health care provider.

The Board approved this Notice of Intended Action during a regularly scheduled meeting on October 3, 2014.

Any interested person may present written comments on the proposed rule not later than 4:30 p.m. on January 15, 2015. Such written materials should be sent to Mark Bowden, Executive Director, Board of Medicine, 400 S.W. Eighth Street, Suite C, Des Moines, Iowa 50309-4686; or sent by e-mail to mark.bowden@iowa.gov.

There will be a public hearing on January 15, 2015, at 1:30 p.m. in the auditorium in the Wallace State Office Building, 502 East Ninth Street, Des Moines, Iowa, at which time persons may present their views either orally or in writing.

After analysis and review of this rule making, it has been determined that this rule could have a positive impact on jobs in Iowa. The new rule will facilitate the practice of medicine at more locations within the state.

This rule is intended to implement Iowa Code chapters 147, 148 and 272C.

The following amendment is proposed.

Adopt the following new rule 653—13.11(147,148,272C):

653—13.11(147,148,272C) Standards of practice—telemedicine. This rule establishes standards of practice for the practice of medicine using telemedicine.

1. The board recognizes that technological advances have made it possible for licensees in one location to provide medical care to patients in another location with or without an intervening health care provider.

2. Telemedicine is a useful tool that, if applied appropriately, can provide important benefits to patients, including increased access to health care, expanded utilization of specialty expertise, rapid availability of patient records, and potential cost savings.

3. The board advises that licensees using telemedicine will be held to the same standards of care and professional ethics as licensees using traditional in-person medical care.

4. Failure to conform to the appropriate standards of care or professional ethics while using telemedicine may subject the licensee to potential discipline by the board.

13.11(1) Definitions. As used in this rule:

“Board” means the Iowa board of medicine.

“In-person encounter” means that the physician and the patient are in the physical presence of each other and are in the same physical location during the physician-patient encounter.

“Licensee” means a medical physician or osteopathic physician licensed by the board.

“Telemedicine” means the practice of medicine using electronic audio-visual communications and information technologies or other means between a licensee in one location and a patient in another location with or without an intervening health care provider. Telemedicine shall not include the provision of medical services only through an audio-only telephone, e-mail messages, facsimile transmissions, or U.S. mail or other parcel service, or any combination thereof.

“Telemedicine technologies” means technologies and devices enabling secure electronic communications and information exchanges between a licensee in one location and a patient in another location with or without an intervening health care provider.

13.11(2) *Nationally recognized telemedicine guidelines.* A licensee who uses telemedicine should be aware that nationally recognized medical specialty organizations have established comprehensive telemedicine practice guidelines that address the clinical and technological aspects of telemedicine for many medical specialties. A licensee who uses telemedicine shall utilize evidence-based telemedicine practice guidelines, to the degree they are available, to ensure patient safety, quality of care, and positive outcomes.

13.11(3) *Iowa medical license required.* A physician who uses telemedicine in the diagnosis and treatment of a patient located in Iowa shall hold an active Iowa medical license.

13.11(4) *Standards of care and professional ethics.* A licensee who uses telemedicine shall be held to the same standards of care and professional ethics as a licensee using traditional in-person encounters with patients. Failure to conform to the appropriate standards of care or professional ethics while using telemedicine may be a violation of the laws and rules governing the practice of medicine and may subject the licensee to potential discipline by the board.

13.11(5) *Scope of practice.* A licensee who uses telemedicine shall ensure that the services provided are consistent with the licensee’s scope of practice, including the licensee’s education, training, experience, ability, licensure, and certification.

13.11(6) *Identification of patient and physician.* A licensee who uses telemedicine shall verify the identity of the patient and ensure that the patient has the ability to verify the identity, licensure status, certification, credentials, and qualifications of all health care providers who provide telemedicine services prior to the provision of care.

13.11(7) *Physician-patient relationship.*

a. A licensee who uses telemedicine shall establish a valid physician-patient relationship with the person who receives telemedicine services. The physician-patient relationship begins when:

- (1) The person with a health-related matter seeks assistance from a licensee;
- (2) The licensee agrees to undertake diagnosis and treatment of the person; and
- (3) The person agrees to be treated by the licensee whether or not there has been an in person encounter between the physician and the person.

b. A valid physician-patient relationship may be established:

(1) Through an in person medical interview and a physical examination (when medically necessary) where an in person encounter would otherwise be required in the provision of the same service not delivered via telemedicine;

(2) Through consultation with another licensee (or other health care provider) who has an established relationship with the patient and who agrees to participate in, or supervise, the patient’s care; or

(3) In accordance with evidence-based telemedicine practice guidelines that are established by nationally recognized medical specialty organizations and address the clinical and technological aspects of telemedicine.

13.11(8) *Medical history and physical examination.* Prior to providing treatment, including issuing prescriptions, electronically or otherwise, a licensee who uses telemedicine shall ensure that the patient is interviewed to collect the patient’s relevant medical history and that the patient receives

a physical examination, when medically necessary, sufficient for the diagnosis and treatment of the patient. Generally, the licensee shall perform an in-person medical interview and a physical examination of the patient. However, the medical interview and physical examination may not be in person if the technology utilized in a telemedicine encounter is sufficient to establish an informed diagnosis as though the medical interview and physical examination had been performed in person. An Internet questionnaire alone does not constitute an acceptable medical interview and physical examination for the provision of treatment, including issuance of prescriptions, electronically or otherwise, by a licensee.

13.11(9) *Nonphysician health care providers.* If a licensee who uses telemedicine relies upon or delegates medical services to a nonphysician health care provider who requires physician supervision, the licensee shall:

a. Personally assess each nonphysician health care provider's education, training, experience and ability to ensure that each provider is qualified and competent to safely perform each medical service being provided;

b. Ensure that each medical service provided is within the scope of practice of the licensee and that of the nonphysician health care provider, as evidenced by the education, training, experience, ability, licensure or certification of the licensee and the nonphysician health care provider;

c. Ensure that the licensee is available electronically to consult with nonphysician health care providers, particularly in the case of injury or an emergency.

13.11(10) *Informed consent.* A licensee who uses telemedicine shall ensure that the patient provides appropriate informed consent for the medical services provided, including consent for the use of telemedicine to diagnose and treat the patient, and that such informed consent is timely documented in the patient's medical record.

13.11(11) *Coordination of care.* A licensee who uses telemedicine shall identify the medical home or treating physician(s) for the patient, when available, where in-person services can be delivered in coordination with the telemedicine services. The licensee shall provide a copy of the medical record to the patient's medical home or treating physician(s).

13.11(12) *Follow-up care.* A licensee who uses telemedicine shall ensure that the patient has access to appropriate follow-up care following a telemedicine encounter. The physician shall have adequate knowledge of the nature and availability of local medical resources to provide appropriate follow-up care to the patient following a telemedicine encounter.

13.11(13) *Emergency services.* A licensee who uses telemedicine shall establish written protocols for referral of the patient to an acute care facility or an emergency department when referral is necessary for the safety of the patient or in the case of an emergency.

13.11(14) *Medical records.* A licensee who uses telemedicine shall ensure that complete, accurate and timely medical records are maintained for the patient when appropriate, including all patient-related electronic communications, records of past care, physician-patient communications, laboratory and test results, evaluations and consultations, prescriptions, and instructions obtained or produced in connection with the use of telemedicine technologies. The licensee shall note in the patient's record when telemedicine is used to provide diagnosis and treatment. The licensee shall ensure that the patient or another licensee designated by the patient has timely access to all information obtained during the telemedicine encounter. The licensee shall ensure that the patient receives, upon request, a summary of each telemedicine encounter in a timely manner.

13.11(15) *Privacy and security.* A licensee who uses telemedicine shall ensure that all telemedicine encounters comply with the privacy and security measures of the Health Insurance Portability and Accountability Act to ensure that all patient communications and records are secure and remain confidential.

a. The licensee shall establish written protocols that address the following:

- (1) Privacy;
- (2) Health care personnel who will process messages;
- (3) Hours of operation;

- (4) Types of transactions that will be permitted electronically;
- (5) Required patient information to be included in the communication, including patient name, identification number and type of transaction;
- (6) Archiving and retrieval; and
- (7) Quality oversight mechanisms.

b. The written protocols should be periodically evaluated for currency and should be maintained in an accessible and readily available manner for review. The written protocols shall include sufficient privacy and security measures to ensure the confidentiality and integrity of patient-identifiable information, including password protection, encryption or other reliable authentication techniques.

13.11(16) *Technology and equipment.* The board recognizes that three broad categories of telemedicine technologies currently exist, including store-and-forward technologies, remote monitoring, and real-time interactive services. While some telemedicine programs are multispecialty in nature, others are tailored to specific diseases and medical specialties. A licensee who uses telemedicine shall ensure that the technology and equipment utilized for telemedicine comply with the following requirements:

a. All technology and equipment utilized must comply with all relevant safety laws, rules, regulations, and codes for technology and technical safety for devices that interact with patients or are integral to diagnostic capabilities;

b. All technology and equipment utilized must be of sufficient quality, size, resolution and clarity such that the licensee can safely and effectively provide the telemedicine services; and

c. All technology and equipment must be compliant with the Health Insurance Portability and Accountability Act.

13.11(17) *Disclosure and functionality of telemedicine services.* A licensee who uses telemedicine shall clearly disclose the following information to the patient:

- a.* Types of services provided;
- b.* Contact information for the licensee;
- c.* Identity, licensure, certification, credentials, and qualifications of all health care providers who are providing the telemedicine services;
- d.* Limitations in the drugs and services that can be provided via telemedicine;
- e.* Fees for services, cost-sharing responsibilities, and how payment is to be made;
- f.* Financial interests, other than fees charged, in any information, products, or services provided by the licensee(s);
- g.* Appropriate uses and limitations of the technologies, including in emergency situations;
- h.* Uses of and response times for e-mails, electronic messages and other communications transmitted via telemedicine technologies;
- i.* To whom patient health information may be disclosed and for what purpose;
- j.* Rights of patients with respect to patient health information; and
- k.* Information collected and passive tracking mechanisms utilized.

13.11(18) *Patient access and feedback.* A licensee who uses telemedicine shall ensure that the patient has easy access to a mechanism for the following purposes:

- a.* To access, supplement and amend patient-provided personal health information;
- b.* To provide feedback regarding the quality of the telemedicine services provided; and
- c.* To register complaints. The mechanism shall include information regarding the filing of complaints with the board.

13.11(19) *Financial interests.* Advertising or promotion of goods or products from which the licensee(s) receives direct remuneration, benefit or incentives (other than the fees for the medical services) is prohibited. Notwithstanding such prohibition, Internet services may provide links to general health information sites to enhance education; however, the licensee(s) should not benefit financially from providing such links or from the services or products marketed by such links. When providing links to other sites, physicians should be aware of the implied endorsement of the information, services or products offered from such sites. The maintenance of a preferred relationship

with any pharmacy is prohibited. Licensees shall not transmit prescriptions to a specific pharmacy, or recommend a pharmacy, in exchange for any type of consideration or benefit from the pharmacy.

13.11(20) *Circumstances when a physician may not personally examine a patient.* Under the following limited circumstances, a licensee may treat a patient who has not been personally interviewed, examined and diagnosed by the licensee:

- a.* Situations in which the licensee prescribes medications on a short-term basis for a new patient and has scheduled or is in the process of scheduling an appointment to personally examine the patient;
- b.* Institutional settings, including writing initial admission orders for a newly hospitalized patient;
- c.* Call situations in which a licensee is taking call for another licensee who has an established physician-patient relationship with the patient;
- d.* Cross-coverage situations in which a licensee is providing coverage for another licensee who has an established physician-patient relationship with the patient;
- e.* Situations in which the patient has been examined in person by an advanced registered nurse practitioner or a physician assistant or other licensed practitioner with whom the licensee has a supervisory or collaborative relationship;
- f.* Emergency situations in which the life or health of the patient is in imminent danger;
- g.* Emergency situations that constitute an immediate threat to the public health including, but not limited to, empiric treatment or prophylaxis to prevent or control an infectious disease outbreak;
- h.* Situations in which the licensee has diagnosed a sexually transmitted disease in a patient and the licensee prescribes or dispenses antibiotics to the patient's named sexual partner(s) for the treatment of the sexually transmitted disease as recommended by the U.S. Centers for Disease Control and Prevention; and
- i.* Certain nursing home and hospice settings.

13.11(21) *Prescribing controlled substances—prohibited.* Prescribing controlled substances to a patient based solely on an Internet request, Internet questionnaire or a telephonic evaluation is prohibited.

13.11(22) *Medications or treatment regimens that can be administered only by a physician.* The licensee must be physically present in the same location as the patient when prescribing, administering, or dispensing medications or providing treatment regimens that can be administered only by a physician, as required by law or administrative rule, by protocols approved by the U.S. Food and Drug Administration, or by appropriate standards of care. Nothing in this rule shall be interpreted to contradict or supersede the requirements established in rule 653—13.10(147,148,272C).

This rule is intended to implement Iowa Code chapters 147, 148 and 272C.